

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

STEVE KLEIN, Individually and on Behalf of)	Case No. 1:21-cv-04181
All Others Similarly Situated,)	
)	<u>CLASS ACTION</u>
Plaintiff,)	
)	Judge Gary Feinerman
vs.)	
)	
ITERUM THERAPEUTICS PLC, et al.,)	
)	
Defendants.)	
)	<u>DEMAND FOR JURY TRIAL</u>
_____)	

**LEAD PLAINTIFFS' COMPLAINT FOR VIOLATIONS OF THE FEDERAL
SECURITIES LAWS**

Lead Plaintiffs Ian Grocher, Thomas L. Sullivan, and Gert-Paul van 't Hoff (“Lead Plaintiffs”), individually and on behalf of all others similarly situated, allege the following based on personal knowledge as to Lead Plaintiffs’ own acts and on information and belief as to all other matters based on the investigation conducted by and through Lead Plaintiffs’ attorneys. This investigation included, among other things, review and analysis of: U.S. Securities and Exchange Commission (“SEC”) filings by Iterum Therapeutics plc (“Iterum” or the “Company”); Iterum’s press releases and earnings call transcripts; public information about Iterum, including information posted on the Company’s website and otherwise available on the internet; and analyst and media reports on Iterum. Lead Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

INTRODUCTION

1. Lead Plaintiffs bring this securities fraud class action on behalf of all purchasers of Iterum common stock between November 30, 2020 and July 26, 2021, inclusive (“Class Period”), against Iterum, its President and Chief Executive Officer (“CEO”) Corey Fishman (“Fishman”), and its Chief Financial Officer (“CFO”) Judith Matthews (“Matthews”) (collectively, “Defendants”). Lead Plaintiffs allege that Defendants violated §§10(b) and 20(a) of the Securities Exchange Act of 1934 (“Exchange Act”) and SEC Rule 10b-5 promulgated thereunder.

2. Iterum is a clinical-stage pharmaceutical company whose sole focus centers on developing a single drug, sulopenem, a novel anti-infective compound with oral (etzadroxil-probenecid) and intravenous (“IV”) formulations. The Company acquired sulopenem from Pfizer, Inc. (“Pfizer”) by way of an exclusive, worldwide license. Iterum describes sulopenem as a potent antibiotic with the potential to be an important new treatment alternative to address growing concerns related to bacteria that have become resistant to antibiotics, especially in uncomplicated urinary tract infections (“uUTIs”).

3. This case involves Defendants' false and misleading statements and material omissions during the Class Period regarding the development, regulatory approval, and commercialization of sulopenem. Throughout the Class Period, Defendants consistently reassured shareholders that the clinical trials for sulopenem were sufficient and conditioned investors to believe that Iterum's November 2020 New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for sulopenem (the "sulopenem NDA") was supported by sufficient, positive data, primed for FDA approval, and that the Company was preparing for a launch of oral sulopenem in the fourth quarter of 2021.

4. Iterum, however, had no other products in development and, leading up to the start of the Class Period, reported a net loss of \$12.2 million for the third quarter of 2020 ended September 30, 2020. As a development-stage pharmaceutical company, Iterum had yet to receive approval for the sale of any drug candidate in any market and, therefore, the Company had not generated any revenue from any product. The Company's business model during the Class Period depended wholly on the successful development, regulatory approval, and subsequent commercialization of sulopenem. In pursuit of this model, Iterum spent substantial cash in connection with its planned product development efforts, clinical trials, and efforts to secure FDA approval of sulopenem, as well as planned commercialization and marketing activities.

5. In addition, Iterum used the announcement of the FDA's acceptance of the sulopenem NDA in January 2021 to secure much-needed capital to fund the Company's operations. Specifically, while the price of Iterum stock was artificially inflated, on February 3, 2021, Iterum announced a stock offering that would generate gross proceeds of \$40 million. Then, on February 9, 2021, Iterum issued another press release announcing an offering, this time via definitive agreements with several healthcare-focused institutional investors, for the purchase and sale of 17,500,000 of Iterum's ordinary shares at a purchase price of \$2.00 per ordinary share in a

registered direct offering priced at-the-market under Nasdaq rules. Iterum stated the offering was expected to generate \$35 million in gross proceeds and close on or about February 12, 2021. With each offering, Iterum stated it would use the offering proceeds, which totaled \$85 million to support Iterum's operations, the sulopenem NDA, and the commercialization of sulopenem.

6. In order to maintain an artificially inflated stock price, the Company conditioned the market to expect that the sulopenem NDA was primed for FDA approval and commercialization in the fourth quarter of 2021, without regard to weaknesses in the sulopenem NDA, as well as communications and feedback from the FDA indicating concerns and issues with the sulopenem NDA. Throughout the Class Period, however, Defendants touted the significant need for sulopenem, highlighting that despite growing concerns regarding antibiotic resistant bacteria, which often require patients to use more potent antibiotics with long lists of side effects, none of the most commonly used oral antibiotics for treatment of uUTIs were initially approved by the FDA within the last two decades.

7. Because of this, the Company stated oral sulopenem would be an important empiric treatment option for elevated risk of uUTI patients because of its potency against antibiotic resistant pathogens, as well as its "spectrum of antibacterial activity." To that end, the primary endpoint of the Company's uUTI Phase 3 clinical trial was designed to demonstrate non-inferiority to ciprofloxacin in patients with quinolone-susceptible pathogens, but also provided Iterum with an opportunity to demonstrate superiority of sulopenem to ciprofloxacin in patients with quinolone-resistant pathogens.¹ Iterum touted that sulopenem had the potential to enable faster

¹ Quinolones, along with fluoroquinolones, are a type of broad-spectrum antibiotic that are effective against a wide range of bacteria. However, because of their risks of serious side effects, the FDA has advised they are not suitable for common conditions, such as uUTIs, and should only be considered when treatment with other, less toxic antibiotics has failed. Ciprofloxacin, for example, is a fluoroquinolone antibiotic that can cause serious side effects.

hospital discharges, providing cost-saving advantages for hospitals and mitigating the risk of other treatment-related infections for patients, such as infections from catheters in the treatment of UTIs.

8. Prior to the Class Period, in the third quarter of 2018, Iterum initiated three Phase 3 clinical trials for sulopenem. The Company completed enrollment in the fourth quarter of 2019, and told investors that topline data from the Company's uUTI and complicated UTI ("cUTI") trials – if the data was positive – would be used to support two NDAs, one for oral sulopenem and one for IV sulopenem, around mid-2020.

9. The Class Period begins on November 30, 2020, when the Company announced its submission of the sulopenem NDA (for oral sulopenem) for the treatment of uUTIs in patients with a quinolone non-susceptible pathogen – meaning for patients infected with a bacteria that was resistant to a quinolone antibiotic. The Company described the submission of the sulopenem NDA as a "significant step forward in bringing new antibiotics to patients to help address the challenge of antibiotic resistance" and told investors the Company was "now one step closer to realizing the goal of bringing this much needed medicine to the over six million patients with cipro-resistant UTIs each year in the U.S." Although the sulopenem NDA included data from all three of the Company's Phase 3 clinical trials (dubbed "SURE-1," "SURE-2," and "SURE-3"), Iterum stated that the SURE-1 clinical trial in uUTIs demonstrated statistical superiority of oral sulopenem to the most widely used comparator, ciprofloxacin, for the primary efficacy endpoint of clinical and microbiologic response "at the test-of-cure visit for patients with a quinolone non-susceptible pathogen."

10. Shortly thereafter, on January 25, 2021, Iterum announced the FDA accepted the oral sulopenem NDA for review for the treatment of uUTIs in patients with a quinolone non-susceptible pathogen; that the FDA designated the application as a priority review and assigned a goal date for completion of the review of July 25, 2021; and that the FDA planned to hold an

Advisory Committee Meeting to discuss the NDA. Defendants touted the FDA's acceptance of the NDA as an "important milestone" for the Company and told investors sulopenem was an "important antibiotic" that was now "one step closer to relieving the growing problem of quinolone resistance found in over six million uncomplicated urinary tract infections in the U.S. each year." Again, Defendants highlighted the data in support of the NDA, which they stated demonstrated statistical superiority of oral sulopenem to ciprofloxacin for the primary efficacy endpoint of the study. Throughout the Class Period, Defendants continued to portray the Company's interactions with the FDA as positive, and repeatedly highlighted the target of commercializing oral sulopenem in the fourth quarter of 2021. Defendants' materially false and misleading statements and omissions had their intended effect, inflating Iterum's common stock price during the Class Period to as high as \$2.73 per share on February 10, 2021.

11. Yet, despite communications from the FDA to Iterum during the Class Period indicating issues with the data underlying the sulopenem NDA, including the red flag of the FDA canceling its Advisory Committee meeting, Defendants not only failed to disclose the substance of the FDA's concerns, but also continued to set market expectations that the drug was on a path for commercialization, which would significantly impact Iterum's financial performance, by the end of 2021. Iterum clearly had a strong incentive to rush the sulopenem NDA to the FDA in an attempt both to access capital through stock offerings and to bring sulopenem to market as quickly as possible. With no existing revenue and a limited cash supply, Iterum's future hinged on being able to convince investors that the Company was poised to sell sulopenem.

12. For example, on May 14, 2021, Iterum disclosed that, although the FDA previously planned to hold an Advisory Committee Meeting for the sulopenem NDA on June 2, 2021, the meeting was "postponed" to allow the FDA "more time to review material provided by the Company in support of the NDA." Iterum told investors that a new date, if required by the FDA,

had not yet been confirmed. Despite this, Defendants assured investors there was no change to the FDA's timeline; that Iterum expected a decision on the drug in the second half of 2021; and that the Company was "preparing for a launch of oral sulopenem into the community in the fourth quarter of 2021, if approved." Characterizing the Company's interactions with the FDA, Fishman stated in the conference call on May 14, 2021 that the Company's interactions with the FDA had "progressed well" and were "typical."

13. Shortly after, on May 27, 2021, Iterum disclosed in a press release that the Company had a meeting with the FDA, where the FDA shared "issues still under review" regarding the sulopenem NDA and informed Iterum that an Advisory Committee meeting was not necessary. Defendants, however, assured investors that Iterum responded to the FDA's issues; that review of the NDA was ongoing; and that the July 25, 2021 Prescription Drug User Fee Act ("PDUFA") goal date remained intact.

14. Analysts responded positively, with RBC Capital Markets stating the Company's communications with the FDA represented a "healthy dialogue" over "routine filing issues over the course of the review." Defendants, however, did not share with investors what the FDA's "issues" were. Defendants' limited disclosures to investors worked, as the price of Iterum stock remained stable in the wake of the May 27, 2021 press release.

15. During the summer of 2021, however, investors learned through several disclosures that there were significant problems at Iterum. First, on June 8, 2021, Iterum Board member Dr. Shazad Malik ("Malik") notified the Company of his immediate resignation from the Board. Rather than replace him, Iterum chose to reduce the Board's size.

16. After the market closed on July 1, 2021, Iterum issued a press release announcing that the Company received a letter – which was *not* disclosed to investors – from the FDA, stating that the FDA had "identified deficiencies" with the sulopenem NDA "that preclude the

continuation of the discussion of labeling and post marketing requirements/commitments at this time.” Despite receiving the letter, the Company kept its content under wraps and only disclosed to investors that Iterum “intend[ed] to work with the FDA to understand the nature of the deficiencies and resolve them as quickly as possible.” Continuing, the July 1, 2021 release quoted Fishman as stating that Iterum “continue[d] to believe in the potential of sulopenem,” and that the Company’s goal had shifted from approval of the sulopenem NDA to “work[ing] with the FDA to identify and resolve the issues” quickly to “continue advancing this much needed antibiotic.”

17. On this news, Iterum’s share price fell an astounding **38%**, or \$0.87, to close at \$1.42 per share on July 2, 2021, on highly elevated trading volume. Despite this steep decline in the price of Iterum stock, Iterum stock remained artificially inflated because Iterum still failed to inform investors of the full nature and extent of the sulopenem NDA’s deficiencies, or the nature and content of the Company’s communications with the FDA.

18. Additional bad news regarding the Company’s failing sulopenem NDA shocked investors before the market opened on July 26, 2021, when Iterum issued a press release announcing that it had received a Complete Response Letter (“CRL”) regarding the sulopenem NDA from the FDA *three days earlier*, on July 23, 2021.² The release described the CRL in general terms, without making it public for investors or explaining why the Company failed to reveal the CRL’s existence for three days. Instead, the release stated that “[t]he CRL provided that the FDA has completed its review of the NDA and has determined that it cannot approve the NDA in its present form.”

² The FDA sends a CRL to communicate it has completed its review of a new drug application and that it has decided *not* to approve it for marketing in its present form. Receiving a CRL is equivalent to the rejection of an NDA.

19. The July 26, 2021 release made clear the Company's sulopenem NDA lacked data needed to support approval of the drug; that the Company would need to conduct at least one additional, time consuming clinical trial; and that the FDA had advised the Company to reevaluate and determine the optimal dosing regimen for oral sulopenem. Specifically, the press release stated:

In the CRL, the FDA acknowledged that the Phase 3 SURE-1 clinical trial demonstrated statistical significance in difference in overall response rate of oral sulopenem compared to ciprofloxacin in the ciprofloxacin-resistant population. However, ***the FDA determined that additional data are necessary to support approval for the treatment of adult women with [uUTIs] caused by designated susceptible microorganisms proven or strongly suspected to be non-susceptible to a quinolone.*** The FDA recommended that Iterum conduct at least one additional adequate and well-controlled clinical trial, potentially using a different comparator drug. Additionally, the FDA recommended that Iterum conduct further nonclinical investigation to determine the optimal dosing regimen, although the FDA stated that this recommendation does not raise an approvability issue. The FDA indicated its willingness to work with Iterum on the design of the clinical trial(s) to address the deficiencies noted.

20. On this shocking news, the price of Iterum stock plummeted once again, falling **44%** to close at \$0.631 per share on July 26, 2021, on unusually high trading volume.

JURISDICTION AND VENUE

21. Lead Plaintiffs assert claims under §§10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§78j(b) and 78t(a), and SEC Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5.

22. This Court has jurisdiction over this case's subject matter pursuant to 28 U.S.C. §§1331 and 1337, and §27 of the Exchange Act, 15 U.S.C. §78aa.

23. Venue is proper in this District under 28 U.S.C. §1391(b)-(c), and §27 of the Exchange Act.

24. Iterum maintains a corporate headquarters for its U.S. operations in this District. Additionally, certain acts and conduct underlying Lead Plaintiffs' allegations, including the

dissemination of materially false and misleading information to the investing public, occurred in this District.

25. In connection with Lead Plaintiffs' allegations, Defendants used the means and instrumentalities of interstate commerce, including the mails, interstate telephone communications, and facilities of the national securities markets.

PARTIES

26. Lead Plaintiffs Ian Grocher, Thomas L. Sullivan, and Gert-Paul van 't Hoff purchased shares of Iterum common stock at artificially inflated prices during the Class Period and suffered damages when that artificial inflation was removed via the corrective disclosures alleged herein. *See* ECF Nos. 19-2, 19-3 (reflecting Lead Plaintiffs' Class Period trades in Iterum common stock).

27. Defendant Iterum Therapeutics plc is a clinical-stage pharmaceutical company with headquarters in Chicago, Illinois and Dublin, Ireland, focused on developing sulopenem, an anti-infective drug for multi-drug resistant pathogens.

28. Defendant Corey Fishman served as Iterum's President and CEO and a member of the Board at all relevant times. Defendant Fishman has served as Iterum's CEO since late 2015 when the Company formed. From 2010 to 2015, Fishman served as CFO and Chief Operating Officer ("COO") of Durata Therapeutics ("Durata").³ Fishman led Durata through its IPO, a secondary public offering, and ultimately Durata's sale to Actavis Generics ("Actavis"), another pharmaceutical company. Fishman has been on the boards of Momenta Pharmaceuticals (Nasdaq: MNTA, acquired by Johnson & Johnson) and BioSpecifics Technology Corporation (Nasdaq: BSTC, acquired by Endo International plc). Fishman received a B.A. in Economics from the

³ Durata, formed in 2009, was a start-up pharmaceutical company focused on developing and commercializing new drugs for patients with infectious diseases and acute illnesses.

University of Illinois at Urbana-Champaign and a Master of Management in Finance from the Krannert School of Management at Purdue University.

29. Defendant Judith Matthews served as Iterum's CFO and Investor Contact at all relevant times. Defendant Matthews has served as Iterum's CFO since late 2015, when the Company formed. Before joining Iterum, Matthews worked as Durata's VP of Finance from 2012 to 2015, until the Actavis acquisition. Matthews received a B.A. in Accounting from the University of Illinois at Urbana-Champaign and a Master of Management in Finance and Marketing from the Kellogg School of Management at Northwestern University.

30. Iterum, Fishman, and Matthews collectively are referred to herein as "Defendants." Fishman and Matthews collectively are referred to herein as the "Individual Defendants."

31. The Individual Defendants, because of their positions within Iterum, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors. Each of the Individual Defendants received in the ordinary course of business copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance, and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations were materially false and/or misleading.

FACTUAL BACKGROUND

32. At bottom, this case is about Defendants' false and misleading statements and omissions of material facts regarding sulopenem, the sulopenem NDA, and Iterum's business and financial outlook, which hinged entirely on Defendants' submission of a viable NDA to secure

additional capital and FDA approval of sulopenem for marketing and sale in the United States. As set forth below, the FDA's highly-regulated process for new drug approval generally takes place across four stages: Pre-Clinical Studies, Clinical Trials, NDA Review, and Post-Marketing.⁴

Stage One: Pre-Clinical Studies

33. The developer of a new drug is called a "sponsor." A sponsor developing a new drug must secure the FDA's approval before marketing or selling it in the United States. To begin the process at Stage One, a sponsor must test a new drug on animals for toxicity, which will result in basic information on the safety and efficacy of the drug under investigation.

34. Next, the sponsor submits an Investigational New Drug ("IND") application to the FDA based on the results of the initial animal testing. The IND includes information about the drug's composition and manufacturing process. The sponsor also submits a proposal for testing the drug on humans in clinical trials. The FDA then reviews the IND to ensure that the proposed clinical trials do not place human subjects at an unreasonable risk of harm and reflect the subjects' informed consent.

Stage Two: Clinical Trials

35. Following a successful proposal, Stage Two involves clinical trials. A typical clinical trial has three phases. Each phase of the clinical trial is designed to investigate a different aspect of the new drug and its effects on humans.

36. Phase 1 clinical trials usually are conducted with healthy volunteers. The goal of Phase 1 is to discover the drug's most common side effects. The number of subjects (the "population") in Phase 1 often ranges between 20 and 80 people.

⁴ The fourth stage, Post-Marketing, is not relevant to this case.

37. Phase 2 clinical trials collect preliminary data on whether the drug actually works in people who have the disease or condition that the new drug aims to treat. Put differently, Phase 2's goal is to discover a drug's efficacy, *i.e.*, whether the drug actually works. In controlled Phase 2 trials, the experiences of patients receiving the drug are compared with those of similar patients receiving a different treatment – usually a placebo or another drug (known as a “comparator”). Despite focusing on efficacy, Phase 2 clinical trials also evaluate the drug's safety and short-term side effects. Sponsors seek to ensure that any positive results are “statistically significant,” meaning that the result from the clinical trial is actually attributable to the drug and did not occur due to randomness or chance. Thus, a Phase 2 clinical trial's population typically numbers in the hundreds.

38. If Phase 2 clinical trial results demonstrate that the drug is effective, Phase 3 clinical trials can begin. After a successful Phase 2 clinical trial, a drug sponsor meets with the FDA to develop a large-scale Phase 3 clinical trial, which gathers even more data about the drug's safety (*i.e.*, whether the benefits of the drug outweigh the known risks) and efficacy. Phase 3 clinical trials also test different populations, dosages, and the drug's interactions with other drugs. A Phase 3 clinical trial's population typically numbers in the thousands.

39. At the end of a clinical trial, the main result measured to see whether a new drug works is called the “primary endpoint.” Meeting the primary endpoint means a new drug was more effective than the placebo or comparator, measured by statistical significance. If a clinical trial does not meet the primary endpoint, it does not show that the new drug was more effective. Clinical trials also monitor any “adverse events,” meaning unfavorable medical occurrences that trial participants experience during the trial's course. Adverse events, for example, may include an abnormal lab finding, symptom, or side effect. Successful clinical trials generate statistically significant data to demonstrate a new drug's safety and efficacy to the FDA.

Stage Three: NDA Review

40. Stage Three's crux is the NDA, the official step through which a drug sponsor formally asks the FDA to consider approving a new drug for marketing and sale in the United States. A drug sponsor typically meets with the FDA before submitting the NDA, which contains everything the FDA needs to know about the new drug: all animal and human testing data, analyses of that data, information about the drug's behavior in the body, and the manufacturing process.

41. If the FDA files the NDA, then the FDA begins to review it.⁵ A team of CDER physicians, chemists, statisticians, pharmacologists, and other scientists review the NDA data to evaluate the sponsor's research on the drug's safety and efficacy. The review team scrutinizes the NDA and searches for possible issues, such as weaknesses in the underlying data and study design. The reviewers then determine whether they agree with the sponsor's results and conclusions, or whether deficiencies in the information underlying the NDA prohibit approval.

42. In addition to the NDA, the FDA reviews the drug's labeling and inspects any facilities where the drug will be manufactured.

43. Finally, after the CDER team completes the NDA review process, the FDA either will approve the application or issue a CRL to the sponsor to say the FDA does not approve the application in its present form. If a sponsor receives a CRL, the sponsor must either: (i) resubmit the NDA, addressing all deficiencies identified in the CRL; (ii) withdraw the NDA without prejudice to a future re-application; or (iii) request a hearing on whether there are grounds for the FDA's denial of the NDA under certain sections of the Federal Food, Drug, and Cosmetic Act.

⁵ The main consumer watchdog of new drugs entering the market is the FDA's Center for Drug Evaluation and Research ("CDER"). Before a new drug can be sold, CDER must evaluate it to ensure the drug is effective and that its health benefits outweigh any known risks.

Prescription Drug User Fee Act

44. In 1992, Congress passed the PDUFA. Under PDUFA, a new drug sponsor agrees to pay fees that enable the FDA to allot additional resources to reviewing NDAs. Under PDUFA, the FDA created a two-tiered system of review timelines: Standard Review and Priority Review. A Priority Review designation means that the FDA usually will take action on an NDA (*i.e.*, either approve the NDA or issue a CRL) within six months – compared to a 10-month timeline under Standard Review.

45. According to the FDA, Priority Review “will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.” The FDA, itself, assigns review designations for each NDA. But a drug sponsor may request Priority Review. Importantly, a Priority Review designation has no effect on either the length of the required clinical trial period nor the scientific or medical standards by which the FDA reviews the NDA.

Contract Research Organizations

46. To execute the clinical trials and other research kindred to new drugs’ development, drug sponsors often hire Contract Research Organizations (“CROs”). CROs are used by pharmaceutical and biotechnology companies to outsource clinical research services. Using CROs can reduce costs for drug sponsors because doing so eliminates the need for pharmaceutical companies to set up and execute in-house clinical trials and research. CROs can be especially attractive to new or start-up pharmaceutical companies navigating the pathway to FDA approval of a drug in development because CROs have superior expertise and resources to conduct the clinical trials.

47. Here, Iterum enlisted CROs to assist with its clinical trials of sulopenem.

Bacteria, Antibiotics, Antibacterial Resistance, and Urinary Tract Infections

48. As set forth above, Iterum sought to have sulopenem approved to treat UTIs, which are caused by bacterial infections. Bacteria are one of the most common pathogens that cause infections in the human body, and antibiotics are generally effective at fighting off bacterial infections. One common category of antibiotics are quinolones, which comprise a large group of broad spectrum antibiotics used to treat a variety of bacterial infections. Many quinolone antibiotics in use are fluoroquinolones, which include ciprofloxacin, often called cipro, one of the most widely used and commonly prescribed fluoroquinolone antibiotics in the world. Cipro is considered to be critically significant to human medicine. While fluoroquinolones often are effective against bacteria, they are not without the risk of serious side effects, including disabling and potentially permanent side effects of the tendons, muscles, joints, nerves, and central nervous system. If an antibiotic easily kills bacteria, such bacteria are considered to be “susceptible” to that antibiotic.

49. However, over time, bacteria can become resistant (or “non-susceptible”) to certain antibiotics. Bacterial resistance essentially means that bacteria develop the ability to defeat the antibiotics designed to kill them. Bacteria can be resistant to quinolones, and quinolone-resistant bacteria pose significant risks to modern medicine.

50. More than 2.8 million antibiotic-resistant infections occur in the U.S. each year, with more than 35,000 people dying annually as a result. According to the CDC, antibiotic-resistant infections can require the use of second- and third-line treatments that can harm patients by causing serious side effects like organ failure and prolonging care and recovery for months. In some cases, these infections have no treatment options. The development of new drugs that fight antibiotic-resistant bacteria is considered to be of great medical importance, and was the focus of Iterum’s efforts with sulopenem.

51. A common type of bacterial infection, which occurs when bacteria get into the urinary tract causing an infection in the bladder area, is a UTI. One type of UTI, the uncomplicated UTI or uUTI, occurs in females with normal anatomy of the urinary tract and is not accompanied by systemic signs or symptoms such as fever or pain outside the pelvic region. On the other hand, UTIs in males and UTIs that are accompanied by signs or symptoms that suggest the spread of infection beyond the urinary tract are characterized as complicated UTIs or cUTIs. Health care providers typically treat UTIs with antibiotics.

52. However, UTIs can be caused, and increasingly are caused, by antibiotic resistant bacteria. This development is making UTI treatment more difficult and can lead to serious complications when some bacteria are able to continue growing and infect the body even after a full course of antibiotics. With the rise of antibiotic resistance due to antibiotics being prescribed unnecessarily or inappropriately, some common antibiotic drugs, such as amoxicillin, no longer can kill off the bacteria that commonly cause UTIs, making the resulting infections more difficult to eliminate, increasing risks to patients, and increasing the burden on the health care system as patients require longer periods of care and experience increased rates of hospitalization rather than treatment at home.

53. Leading up to and during the Class Period, Iterum regularly touted the need for sulopenem. For example, Fishman stated in a press release on December 26, 2019, that “[i]t has been over 20 years since a new, oral treatment has been developed for urinary tract infections and the existing orals are no longer effective. If approved, oral sulopenem will provide an option to those patients with an elevated risk for treatment failure that currently have no other alternatives.” In that vein, leading up to and during the Class Period, Iterum heralded sulopenem to the market as medicine’s next big development to combat uUTIs caused by bacteria resistant to other antibiotics.

The Historical Development of Sulopenem and the Individual Defendants' Experience at Durata

54. Sulopenem originally belonged to Pfizer, a multinational pharmaceutical and biotechnology company. Pfizer shelved its attempts to develop sulopenem around 2009, along with other anti-infectives in Pfizer's portfolio, because its costly research and development ("R&D") failed to generate clinically competent or statistically significant data necessary to support regulatory approval. As alleged above, such data is necessary to support successful submission of an NDA to the FDA.

55. Among the anti-infectives shelved by Pfizer were drugs that Fishman, Matthews, and other current Iterum senior staff and Board members collaborated on, before Iterum's inception, while working as officers and directors of Durata. For example, at Durata, Fishman, Matthews, and Dr. Michael Dunne ("Dunne"), among others, oversaw the continued development of dalbavancin, an antibiotic used to treat skin infections, which Durata bought from Pfizer in 2009.

56. There was significant overlap between the leadership of Iterum and Durata. At the time of Durata's clinical trials of dalbavancin, Dunne, who previously served as a VP in Pfizer's global drug development program, was Durata's Chief Medical Officer ("CMO"). Dunne would go on to become Iterum's Chief Scientific Officer ("CSO") and he is on Iterum's Board, both as a member and strategic advisor. Iterum's President and CEO, Fishman, was Durata's former COO/CFO from August 2010 to February 2015. Iterum's CFO and Investor Contact, Matthews, was Durata's VP Finance & Accounting from June 2012 to February 2015. And Iterum Board members Brenton Ahrens, Beth Hecht, and Ronald Hunt were formerly Durata Board members. As such, a large number of Iterum's senior management and the Board (currently and at all relevant times), held leadership positions at Durata. Indeed, five of Iterum's seven directors were involved with Durata.

57. While Pfizer was developing dalbavancin, the FDA changed its rules for approval and rejected Pfizer's attempt, leading Pfizer to give up on the drug rather than conduct additional, time-consuming, and expensive clinical trials. Specifically, the FDA told Pfizer in 2007 that dalbavancin could not be approved because the dalbavancin NDA lacked "an adequate justification for a noninferiority margin." Essentially, the NDA lacked evidence from an adequate well-controlled study to support the drug's approval.

58. Durata undertook to continue the R&D of dalbavancin, but ultimately fell short on money to finance the necessary late stage, Phase 3 clinical trials. To compensate, Durata struck a deal with Pfizer for \$6 million to conduct trials on dalbavancin in exchange for contingent milestone payments of \$25 million to Pfizer if the FDA approved dalbavancin and the drug reached the market.

59. Five years after Durata purchased dalbavancin, the FDA approved the drug to treat acute bacterial skin and skin structure infections in late 2014. Soon after, Actavis bought out Durata and dalbavancin for \$675 million – or \$23 per share when, prior to the buyout, Durata's stock was trading at \$11 per share.

60. Shortly after the Durata buyout, Fishman, Matthews, Dunne, and former Durata Board members Brenton Ahrens, Beth Hecht, and Ronald Hunt formed Iterum and licensed sulopenem from Pfizer. Iterum, backed by a majority of the same entities that funded Durata, was promising to investors who believed that Defendants could resurrect yet another anti-infective from Pfizer's shelf.

61. As alleged above, sulopenem is a development stage antibiotic drug intended to treat bacterial infections. Pfizer completed an extensive pre-clinical program (Stage One) and a number of clinical trials (Stage Two) for sulopenem. Pfizer ceased development of sulopenem around 2009, and had failed to generate any statistically significant data on sulopenem through its

expensive R&D efforts. Dunne played a significant role in helping Iterum secure an exclusive license with Pfizer in November 2015 for sulopenem (the “Pfizer License”).⁶

62. In June 2017, almost two years after the Pfizer License took effect, Dunne touted sulopenem in an interview with *Forbes*, stating:

[Sulopenem’s] main attraction is the fact that, in addition to an intravenous preparation, it is orally available, which will allow for step-down therapy for hospitalized patients coming off their IV therapy, as well as treatment of outpatient infections due to resistant pathogens. Having worked on sulopenem while I was at Pfizer, I recognized its continued relevance to today’s problem of multidrug resistant infections. Pfizer quickly recognized it would be better to have someone continue the development efforts rather than have the drug just sit on the shelf. The license is fairly typical for these types of compounds but, unless Iterum chooses not to develop it further, there are no claw back rights.⁷

63. Since Iterum’s inception, the Company’s sole business focus has been the development and commercialization of sulopenem, which Iterum has characterized as a potential game-changing medication in the face of increasing antibiotic resistant bacteria, while operating at a significant financial loss and attempting to navigate sulopenem’s pathway to FDA approval through the sulopenem NDA and underlying clinical trials. While Pfizer previously, and unsuccessfully, sought to develop sulopenem to treat pneumonia, Iterum sought to develop sulopenem as a treatment for uUTIs. The Company’s business and financial outlook have hinged entirely on whether Defendants could raise enough capital and submit a successful sulopenem NDA and secure FDA approval of the drug for marketing and sale in the United States. As a result, Defendants’ statements regarding sulopenem were of critical importance to Iterum investors and

⁶ Under the Pfizer License, Pfizer received, and still stands to gain, considerable financial interests in Iterum’s successful commercialization of sulopenem.

⁷ John LaMattina, *Former Pfizer Scientist Is Resurrecting Projects To Solve The Multidrug Resistant Bacteria Problem*, FORBES (June 13, 2017, 8:06 AM) <https://www.forbes.com/sites/johnlamattina/2017/06/13/former-pfizer-scientist-is-resurrecting-projects-to-solve-the-multidrug-resistant-bacteria-problem/?sh=632a10e1365f>.

the price of Iterum stock, as well as the Company's much-needed ability to raise funds through offerings to investors.

Iterum's Failed Attempt to Secure FDA Approval of Sulopenem to Treat uUTIs

64. In June 2017, before Iterum even began clinical trials on sulopenem, Dunne told *Forbes* that, “[g]iven the medical need it addresses, we believe there is a strong and attractive business rationale for sulopenem.”⁸

65. In the third quarter of 2018, Iterum began its SURE Phase 3 clinical trials, known as SURE-1, SURE-2, and SURE-3, respectively testing sulopenem on uUTIs, cUTIs, and complicated intra-abdominal infections (“cIAIs”).⁹

66. To drive up the stock price and serve their own financial interests, Iterum and the Individual Defendants routinely claimed to investors that “[IV] sulopenem and oral sulopenem have the potential to be important new treatment alternatives to address growing concerns related to [antibiotic] resistance,” and touted that sulopenem would be able to do so “without the known toxicities of some of the most widely used antibiotics, specifically fluoroquinolones.” In other words, Iterum touted its development of sulopenem as a potentially revolutionary drug to fight bacteria that had become resistant to common antibiotics, like penicillin, while also being a safer alternative to fluoroquinolones, such as ciprofloxacin.

67. SURE-1 compared oral sulopenem to oral cipro in women with a uUTI.¹⁰ SURE-1 results showed that the percentages of patients experiencing treatment-related adverse events

⁸ *Id.*

⁹ Iterum used PSI as its CRO to conduct the SURE-1 clinical trial.

¹⁰ SURE-2 compared IV sulopenem followed by oral sulopenem to IV ertapenem (another antibiotic) followed by oral cipro in adults with a cUTI. SURE-3 compared IV sulopenem followed by oral sulopenem to IV ertapenem followed by oral cipro and oral metronidazole (another antibiotic) in adults with a cIAI.

from sulopenem and cipro (*i.e.*, the comparator) were 17.0% and 6.2%, respectively. This means that more patients experienced adverse events taking sulopenem than cipro by a factor of almost three.

68. As mentioned, the SURE-1 study was a Phase 3 clinical trial. To that end, Iterum never conducted any of its own Phase 2 sulopenem clinical trials on patients with uUTIs.¹¹ Rather, the Phase 2 data on which Iterum ultimately relied in the sulopenem NDA – and to proceed to Phase 3 – was from a Phase 2 clinical trial conducted by Pfizer around 2009. Importantly, this Phase 2 clinical trial did not test sulopenem on patients with uUTIs, but instead tested the drug on patients with pneumonia. Further, Pfizer’s Phase 2 clinical trial did not yield statistically significant data.

69. Additionally, the SURE-1 study was Iterum’s only Phase 3 clinical trial testing oral sulopenem on patients with uUTIs. This single study employed a “novel” design¹² and used cipro as the comparator drug. Both aspects cut against industry standards and conventional wisdom and methods for obtaining FDA approval of a new drug. For example, the Mayo Clinic has said that “[t]he group of antibiotic medicines known as fluoroquinolones – such as ciprofloxacin (Cipro), levofloxacin and others – isn’t commonly recommended for simple UTIs, as the risks of these medicines generally outweigh the benefits for treating uncomplicated UTIs.”

70. In December 2019, Iterum announced that sulopenem did not meet the primary endpoint of statistical non-inferiority compared to the control therapy for the SURE-3 cIAI trial.

¹¹ In fact, in Iterum’s own protocol for the SURE-1 clinical trial, Iterum stated: “Phase 2 studies in patients with urinary tract infection[s] . . . have not been conducted in the United States.” *Clinical Trial Protocol: IT001-301*, March 2018, https://clinicaltrials.gov/ProvidedDocs/98/NCT03354598/Prot_000.pdf at 19.

¹² *Id.*

On June 1, 2020, Iterum announced in a press release that, in the SURE-2 cUTI trial, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to the control therapies.

71. Leading up to the Class Period, however, Defendants extolled the data on sulopenem, including past clinical data developed by Pfizer, to rally investors' confidence in not only sulopenem's market potential, but Iterum's ability to submit a successful NDA, secure FDA approval, and begin commercialization of the drug.

72. For example, on June 29, 2020, Iterum issued a press release announcing its topline results from its SURE-1 Phase 3 clinical trial of oral sulopenem for the treatment of uUTIs. The study had two independent primary endpoints. The release acknowledged that sulopenem did not meet one primary endpoint compared to ciprofloxacin in the SURE-1 clinical trial. However, it added that "achievement of either of those endpoints [was] expected to provide a potential path to marketing approval based on previous discussions with the [FDA]," and that the SURE-1 trial was successful because "sulopenem achieved the related primary endpoint by demonstrating superiority to ciprofloxacin, providing substantial evidence of a treatment effect in patients with uUTI," and that those results were "highly statistically significant."

73. The June 29, 2020 press release continued that in a "second population of patients with organisms susceptible to quinolones, sulopenem was not non-inferior to ciprofloxacin and did not achieve the related primary endpoint[.]"¹³ Touting the study's results, the release quoted Fishman: "We are extremely pleased to have a potential path to approval for sulopenem in uUTI." The press release further quoted Fishman highlighting the unique opportunity sulopenem presented: "Sulopenem is the first new oral antibiotic to demonstrate success in treating uUTIs in a phase 3 trial in over twenty years," and "[w]e anticipate a pre-NDA meeting with the FDA in the

¹³ The press release stated the difference in outcomes was driven by the rate of asymptomatic bacteriuria post treatment.

third quarter of 2020 to discuss a path forward.” In parallel, the Company was “evaluating its corporate, organizational, strategic, financial and financing alternatives with the goal of maximizing value for its stakeholders, while prudently managing its resources.”

74. Dunne went even further in extolling the sulopenem clinical trial results, and was quoted in the press release as stating:

Superiority trials to define the effectiveness of novel antibacterial agents are rarely performed but remain the ultimate test for defining the value of a new agent in an area of high unmet medical need. Sulopenem has demonstrated efficacy in the treatment of UTI due to a quinolone resistant organism, a scenario found in almost 30% of all urinary tract infections in women in the United States today.

75. Shortly before the Class Period, Defendants continued to assure investors of a path forward for sulopenem even as Iterum racked up substantial financial losses, including a loss of more than \$51 million in 2020. In a press release dated September 30, 2020, Fishman stated that “we have confidence in our decision to move forward with our NDA package for sulopenem.”

76. Additionally, on October 19, 2020, Iterum announced in a press release that Dunne would present the results of the sulopenem clinical trials at the Infectious Disease Society of America IDWeek, again stating that sulopenem was superior to cipro in treating quinolone-resistant uUTIs.

Sulopenem’s Development Left Iterum in Need of Funding and Created Financial Incentives for Defendants to Rush the Sulopenem NDA

77. The costly R&D associated with the development of sulopenem left Iterum strapped for cash to pay CROs to conduct the expensive, late stage Phase 3 clinical trials of sulopenem necessary to support a viable NDA. To that end, on January 17, 2020, Iterum announced its entry

into a securities purchase agreement with a group of accredited investors for an approximately \$52 million private placement.¹⁴

78. As part of the private placement, Iterum sold nearly 52,000 units, consisting of various debt instruments, some of which were convertible into ordinary shares of Iterum common stock. Iterum sold debt in the form of 6.500% exchangeable senior subordinated notes (“Exchangeable Notes”) and limited recourse royalty-linked senior subordinated notes (“RLNs”).¹⁵ Specifically, Iterum sold this debt in discrete units, each consisting of \$1,000 in principal of Exchangeable Notes and 50 RLNs. In total, Iterum sold approximately \$52 million worth of Exchangeable Notes and RLNs.¹⁶

79. Seeing an opportunity to secure a controlling interest in the Company, activist investor Alex Denner (“Denner”) and affiliates of his investment fund Sarissa Capital Management LP (“Sarissa”) purchased 15,000 units of debt in the private placement. The two largest investors in the private placement were Sarissa Capital Offshore Master Fund LP and Sarissa Capital Catapult Fund LLC.¹⁷ These investors purchased 9,000 and 3,439 units of debt, respectively.¹⁸ Both of these funds are affiliated with Sarissa Capital Management LP, who also led the private placement. In connection with the private placement, Sarissa became entitled to control up to two

¹⁴ Iterum Therapeutics Bermuda Limited, a wholly-owned subsidiary of Iterum Therapeutics plc, was the actual issuer.

¹⁵ The RLNs would entitle holders payments based on a percentage of Iterum’s net revenues from potential sales of sulopenem products.

¹⁶ Because this was a private placement, these debt securities were not registered under the Securities Act of 1933 and could not be offered or sold in the United States without registration.

¹⁷ Sarissa Capital Hawkeye Fund LP also purchased 2,561 units worth \$2,561,000 principal in Exchangeable Notes and 128,050 RLNs.

¹⁸ As such, Sarissa Capital Offshore Master Fund LP received \$9,000,000 principal in Exchangeable Notes and 450,000 RLNs. Sarissa Catapult received \$3,439,000 principal in Exchangeable Notes and 171,950 RLNs.

seats on Iterum's Board, if Sarissa and its affiliates owned more than 12.5% of Iterum's outstanding ordinary shares.

80. Iterum stated that it expected to use the proceeds of the private placement to "fund the continued clinical development of sulopenem and the management of regulatory filings."

81. Meanwhile, Fishman, Matthews, and Dunne each had a powerful personal incentive to quickly put the sulopenem NDA before the FDA, even if the underlying data was insufficient and regardless of whether the FDA expressed concerns with the clinical trial data that jeopardized the NDA's chances for approval. Specifically, in February 2020, Iterum's Compensation Committee approved the grant of performance restricted stock units ("PSUs") to Fishman, Matthews, and Dunne, with 50% of those PSUs scheduled to vest when the FDA accepted the NDA for review, and the remaining 50% scheduled to vest on the date which the FDA set to complete its review of that NDA, as long as both events occurred on or before December 31, 2021.

82. In November 2020, Iterum submitted the sulopenem NDA for oral sulopenem to treat uUTIs in patients with a quinolone non-susceptible pathogen. As Defendants pushed through the sulopenem NDA, in part to serve their own financial interests, prior to and during the Class Period, Defendants assured the market they were working diligently to secure FDA approval, frequently touting the drug's benefits and the lucrative business Iterum would enjoy upon approval of the sulopenem NDA.

83. Specifically, on November 30, 2020, the first day of the Class Period, Iterum issued a press release during pre-market hours announcing its submission of the sulopenem NDA to the FDA. The release stated: "The SURE-1 clinical trial (uUTIs) demonstrated statistical superiority of oral sulopenem to the widely used comparator, ciprofloxacin, for the primary efficacy endpoint

of clinical and microbiologic response at the test-of-cure visit for patients with a quinolone non-susceptible pathogen.” The release continued:

The submission of the NDA filing for oral sulopenem is a significant step forward in bringing new antibiotics to patients to help address the challenge of antibiotic resistance. . . . Oral sulopenem, if approved, would mean that physicians and patients have the opportunity to benefit from the proven efficacy and safety of penem antibiotics that, to date in the U.S., have only been available in IV formulations. We are now one step closer to realizing the goal of bringing this much needed medicine to the over six million patients with cipro-resistant UTIs each year in the U.S.

84. On January 25, 2021, Iterum issued a press release entitled, “[Iterum] Announces U.S. FDA Filing Acceptance of New Drug Application for Oral Sulopenem.” The release noted: “The FDA has designated this application as a priority review and consequently assigned a PDUFA (Prescription Drug User Fee Act) goal date for completion of the review of oral sulopenem of July 25, 2021.” The FDA’s acceptance of the sulopenem NDA resulted in 50% of Fishman, Matthews, and Dunne’s PSUs vesting immediately.

85. While the FDA reviewed the sulopenem NDA, Defendants continued to tout the drug, the NDA, and its supporting clinical data and documentation. Defendants also spun favorably the FDA’s expedited review timeline and the Company’s interactions with the FDA. As set forth below, Defendants strongly indicated the FDA was satisfied with Iterum’s clinical development of sulopenem for treatment of uUTIs and was likely to approve the sulopenem NDA, unlocking lucrative financial opportunities for the Company. But Defendants, in haste to submit the sulopenem NDA, oversold the likelihood of the FDA approving it.

86. For example, the Company’s May 14, 2021 press release stated:

We continue to prepare for a[n FDA] advisory committee meeting and look forward to clarity from the FDA on timing. In the meantime, the FDA continues its review of [the sulopenem NDA] and has not advised us of any change to the current PDUFA goal date of July 25, 2021. . . . With an FDA decision on oral sulopenem expected in the second half of 2021 and a strong cash position, we are preparing for a launch of oral sulopenem into the community in the fourth quarter of 2021, if approved.

87. While the price of Iterum's common stock was inflated, before the FDA's determination on the sulopenem NDA came down, Defendants sold stock. On January 26, 2021, the day after Iterum announced the FDA's acceptance of the sulopenem NDA for review and half the executives' PSUs vested, Fishman sold 85,445 of his shares at \$1.73 per share for total proceeds of approximately \$147,820 – the first time Fishman ever sold any of his Iterum stock. That same day, Matthews sold 33,868 of her shares at \$1.73 each for total proceeds of approximately \$58,591. Sarissa and Denner likewise converted all of their debt instruments to common stock to secure a 30.7% equity stake in Iterum on February 10, 2021, shortly after the FDA accepted the sulopenem NDA and prior to revelations of any problems with the NDA, and immediately dumped their 30.7% ownership interest in the Company for proceeds of approximately \$52,000,000 in February 2021, abandoning their option to take a controlling interest in Iterum.

88. The FDA's acceptance of the sulopenem NDA also provided Iterum the opportunity to secure much needed capital for the Company. On February 3, 2021, Iterum announced its entrance into an underwriting agreement with H.C. Wainwright & Co, LLC ("H.C. Wainwright"), under which the underwriter agreed to purchase on a firm commitment 8,695,653 ordinary shares (or pre-funded warrants in lieu thereof) at a public offering price of \$1.15 per share, less underwriting discounts and commissions. In addition, Iterum granted H.C. Wainwright an option for a period of 30 days to purchase up to an additional 1,304,347 ordinary shares on the same terms and conditions. The release stated that all of the shares (or pre-funded warrants) were being offered by Iterum, and that the offering was expected to close on February 8, 2021. The Company stated that the gross proceeds of the offering, expected to be approximately \$10 million, would be used to support the sulopenem NDA, "for pre-commercialization and potential launch activities for oral sulopenem, and for working capital and general corporate purposes." The February 3, 2021 release

added that with the closing of the offering, the Company's cash position "should be sufficient to fund its operating expenses and capital expenditure requirements into the first quarter of 2022, including through the PDUFA goal date of July 25, 2021 for completion of the FDA's review of the NDA for oral sulopenem."

89. On February 3, 2021, Iterum issued another press release announcing that due to heightened demand, which had been fueled by Defendants' statements regarding sulopenem, H.C. Wainwright had agreed to increase the size of the offering and purchase 34,782,609 ordinary shares (or pre-funded warrants in lieu thereof) at a public offering price of \$1.15 per share, less underwriting discounts and commissions. The Company also granted H.C. Wainwright an option for a period of 30 days to purchase up to an additional 5,217,391 ordinary shares on the same terms and conditions, with the offering still expected to close on February 8, 2021. The release indicated the upsized offering would generate gross proceeds of \$40 million.

90. On February 9, 2021, Iterum issued another press release announcing an offering, this time via definitive agreements with several healthcare-focused institutional investors, for the purchase and sale of 17,500,000 of Iterum's ordinary shares at a purchase price of \$2.00 per ordinary share in a registered direct offering priced at-the-market under Nasdaq rules. Iterum stated the offering, with H.C. Wainwright acting as the exclusive placement agent, was expected to generate \$35 million in gross proceeds, and was expected to close on or about February 12, 2021. Once again, Iterum stated it would use the offering proceeds to support the sulopenem NDA and commercialization of sulopenem.

DEFENDANTS' FRAUDULENT SCHEME, FALSE AND MISLEADING STATEMENTS, AND MATERIAL OMISSIONS

November 2020 False and Misleading Statements

91. The Class Period begins on November 30, 2020, when, before the market opened, Iterum issued a press release announcing that the Company had submitted the sulopenem NDA to

the FDA (the “November 2020 Press Release”). The November 2020 Press Release told investors that the sulopenem NDA included data from the SURE-1, SURE-2, and SURE-3 Phase 3 clinical trials, and added that “[t]he SURE-1 clinical trial (uUTIs) demonstrated statistical superiority of oral sulopenem to the widely used comparator, ciprofloxacin, for the primary efficacy endpoint of clinical and microbiologic response at the test-of-cure visit for patients with a quinolone non-susceptible pathogen.”

92. The November 2020 Press Release also quoted Defendant Fishman as stating:

The submission of the NDA filing for oral sulopenem is a significant step forward in bringing new antibiotics to patients to help address the challenge of antibiotic resistance. . . . Oral sulopenem, if approved, would mean that physicians and patients have the opportunity to benefit from the proven efficacy and safety of penem antibiotics that, to date in the U.S., have only been available in IV formulations. We are now one step closer to realizing the goal of bringing this much needed medicine to the over six million patients with cipro-resistant UTIs each year in the U.S.

93. On December 23, 2020, Iterum announced that Dr. Dunne, who was key to the development of sulopenem, had resigned from his role as Iterum’s chief scientific officer, effective December 20, 2020. Despite stepping down from his role, Dr. Dunne agreed to be a strategic advisor to the Company and was being elected to the Board, effective as of December 22, 2020. Iterum announced that the Company’s Senior Vice President and Head of Clinical Development, Dr. Steve Aronin, would lead the Company’s development and regulatory activities following the effective date of Dr. Dunne’s resignation.

January and February 2021 False and Misleading Statements

94. On January 25, 2021, Iterum issued a press release announcing that the FDA had accepted the sulopenem NDA for review (“January 2021 Press Release”). The January 2021 Press Release continued: “The FDA has designated this application as a priority review and consequently assigned a PDUFA (Prescription Drug User Fee Act) goal date for completion of the review of

oral sulopenem of July 25, 2021.” The January 2021 Press Release also included the following statement from Fishman touting the “important milestone” for the Company:

The FDA acceptance of our NDA for review is an important milestone for Iterum. If approved, oral sulopenem would be the first penem available orally in the U.S. with the ability to treat multi-drug resistant infections in the community. . . . Specifically, this important antibiotic is one step closer to relieving the growing problem of quinolone resistance found in over six million [uUTIs] in the U.S. each year.

95. On February 1, 2021, the Company issued a press release announcing its partnership with EVERSANA, a provider of commercial services to the life science industry, to “immediately initiate pre-launch activities, ***followed by planned commercialization services upon final agreement.***” The release added that, “[a]head of an anticipated decision by the FDA in July 2021, Iterum will utilize EVERSANA’s pre-launch activities including U.S. market access, strategic marketing, medical education, and patient services.” The release reiterated that the FDA had designated the sulopenem NDA for priority review and had a goal date for completion of the review of oral sulopenem of July 25, 2021. The release also quoted Fishman as stating:

We are very pleased to partner with EVERSANA and are confident in their ability to provide end-to-end services to ensure oral sulopenem will reach patients and their families efficiently and effectively once oral sulopenem is available for prescribing. . . . We will be working diligently to ensure we are ready for the potential launch of oral sulopenem in the U.S. in the fourth quarter of 2021.

96. Underscoring the Company’s need for capital, as well as the need to rapidly secure FDA approval of the sulopenem NDA, on February 3, 2021, Iterum announced its entrance into an underwriting agreement with H.C. Wainwright, under which the underwriter agreed to purchase on a firm commitment 8,695,653 ordinary shares (or pre-funded warrants in lieu thereof) at a public offering price of \$1.15 per share, less underwriting discounts and commissions. In addition, Iterum granted H.C. Wainwright an option for a period of 30 days to purchase up to an additional 1,304,347 ordinary shares on the same terms and conditions. The release said that all of the shares (or pre-funded warrants) were being offered by Iterum, and that the offering was expected to close

on February 8, 2021. The Company stated that the gross proceeds of the offering, expected to be approximately \$10 million, would be used to support the sulopenem NDA, “for pre-commercialization and potential launch activities for oral sulopenem, and for working capital and general corporate purposes.” The release added that, with the closing of the offering, the Company’s cash position “should be sufficient to fund its operating expenses and capital expenditure requirements into the first quarter of 2022, including through the PDUFA goal date of July 25, 2021 for completion of the FDA’s review of the NDA for oral sulopenem.”

97. On February 3, 2021, Iterum issued another press release announcing that, due to demand, H.C. Wainwright had agreed to increase the size of the offering and purchase 34,782,609 ordinary shares (or pre-funded warrants in lieu thereof) at a public offering price of \$1.15 per share, less underwriting discounts and commissions. The Company also granted H.C. Wainwright an option for a period of 30 days to purchase up to an additional 5,217,391 ordinary shares on the same terms and conditions, with the offering still expected to close on February 8, 2021. The release indicated the upsized offering would generate gross proceeds of \$40 million.

98. On February 9, 2021, Iterum issued yet another press release announcing an offering, this time via definitive agreements with several healthcare-focused institutional investors for the purchase and sale of 17,500,000 of Iterum’s ordinary shares at a purchase price of \$2.00 per ordinary share in a registered direct offering priced at-the-market under Nasdaq rules. Iterum stated the offering, with H.C. Wainwright acting as the exclusive placement agent, was expected to generate \$35 million in gross proceeds, and was expected to close on or about February 12, 2021. Once again, Iterum stated it would use the offering proceeds to support the sulopenem NDA and commercialization of sulopenem.

March 2021 False and Misleading Statements

99. On March 12, 2021, Iterum issued a press release announcing its fourth quarter and full year 2020 financial results (the “4Q2020 Press Release”). The 4Q2020 Press Release quoted Defendant Fishman as stating, in relevant part:

We estimate that the market for th[e sulopenem NDA’s] indication is approximately 6.5 million uUTIs caused by a quinolone non-susceptible organism annually in the U.S. ***Our priorities for the rest of this year are: (1) holding a positive Advisory Committee meeting in June, (2) completion of FDA review of our NDA by the end of July, (3) initiating the commercial launch in the fourth quarter, if approved, and (4) working with the FDA to understand the requirements for potential expansion of our label in uUTI to include all patients, if approved, and to potentially add the complicated urinary tract infection (cUTI) indication. In anticipation of these key milestones, we have raised sufficient capital to support the execution of our strategy as currently planned.***

100. The 4Q2020 Press Release also highlighted that, in February 2021, the Company received total net proceeds of \$74.3 million from the above-referenced stock offerings which, along with proceeds received from the exercise of certain warrants and existing cash and cash equivalents, “has extended [Iterum’s] cash runway into the first half of 2023, based on [the Company’s] current operating plan.”

101. On March 12, 2021, Iterum filed with the SEC its annual report on Form 10-K for 2020 (the “2020 10-K”). The 2020 10-K assured investors that the Company had made an informed NDA submission based on prior communications with the FDA. The 2020 10-K contained the following false and misleading statements:

In the second quarter of 2020, we announced the results of our Phase 3 clinical trials of sulopenem for the treatment of cUTI and uUTI. In the cUTI trial, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to the control therapies with the difference in response rates driven almost entirely by higher rates of asymptomatic bacteriuria (ASB) on the sulopenem IV to oral sulopenem arm relative to the ertapenem IV to oral ciprofloxacin arm, only evident at the test of cure visit. The rates of patients receiving additional antibiotics or with residual cUTI symptoms were similar between therapies. Similarly, in the uUTI trial, sulopenem did not meet the primary endpoint of statistical non-inferiority compared to ciprofloxacin, in the population of patients with baseline pathogens susceptible to ciprofloxacin driven to a large degree by a greater amount of ASB in

the sulopenem treated patients at the test of cure visit relative to those receiving ciprofloxacin. ***However, in the uUTI trial, in the population of patients with baseline pathogens resistant to quinolones, sulopenem achieved the related primary endpoint by demonstrating superiority to ciprofloxacin, providing evidence of a treatment effect in patients with uUTI.*** Based on discussions with the FDA at a pre-New Drug Application, or NDA, meeting in September 2020 and previous correspondence with the FDA, we submitted an NDA for oral sulopenem for the treatment of uUTIs in patients with a quinolone non-susceptible pathogen in the fourth quarter of 2020 and the FDA accepted the application for review in January 2021.

102. The 2020 10-K added that the FDA “currently plans to hold an advisory committee meeting on June 2, 2021 to discuss the NDA.” It also touted the market potential for sulopenem, stating, “we believe ***there is a pressing need for a novel oral antibacterial therapy for UTI, both complicated and uncomplicated***, that has potent activity against ESBL producing and quinolone resistant gram-negative organisms.”¹⁹ The 2020 10-K further touted that Iterum’s sulopenem program had “the potential to offer a solution to the problem of antibiotic resistance and the limitations of existing agents” and highlighted sulopenem’s “differentiating characteristics,” including its ability to be taken orally, its activity against multidrug resistant pathogens, and its safety and tolerability profile, among other things.

103. The 2020 10-K stated that Iterum expected the “***commercial opportunity for oral sulopenem to be substantial*** with initial focus on the treatment of uUTIs caused by a quinolone non-susceptible pathogen in the community,” and that the size of Iterum’s initial market would be 6-7 million infections annually.

104. The 2020 10-K also contained certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”), signed by Defendants Fishman and Matthews, which certified that “[t]he [2020 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act]” and

¹⁹ ESBL refers to extended spectrum B-lactamases that produce E. coli, a bacteria primarily responsible for patients suffering from UTIs and that is growing increasingly resistant to many classes of antibiotics.

“does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]”

105. On the same day, March 12, 2021, Defendants held a conference call to discuss the Company’s 4Q 2020 results and made the following statements:

(a) With regard to the status of the sulopenem NDA, Fishman stated:

With regard to the [FDA Advisory Committee meeting], the review has been ongoing. I would call it a pretty standard review based on the questions we’ve gotten and in our ability to respond to them. There hasn’t been anything flagged by FDA to us as this will be a topic for discussion at the Advisory Committee. I think we feel very good that we have a very robust data package for our indication, and as I mentioned the data that has been provided in other studies and even in places where we didn’t hit the endpoint has continued to be highly supportive. . . . And so I think the overall package is extremely supportive and I think from an AdCom perspective we’re going in – we’ll be prepared to discuss, of course, the data package and everything around it, but I think we feel good about coming out of there in good shape.

(b) Fishman further stated:

[W]e haven’t gotten any indication that anything is off track. We continue to get indications that we’re still on track for everything we’ve said to-date and the information we provided has been pretty extensive. So, we’ll just have to wait and see but as of today, we don’t have any indication that anything is different than what we had expected.

* * *

[W]e’ve all sort of kept up to-date on what’s happening in other places, but I would say as we sit here today, we feel like this has been a pretty standard kind of review and there’s been no shift in the last month or six weeks in terms of tone or anything like that. We’re getting information requests, which is very typical. We’re responding to those on the timelines were (sic) suggested. And I think we feel like there’s been no change in our review at this point and nothing points us in a direction that looks, anything like that as we sit here, as we are talking today.

May 2021 False and Misleading Statements

106. On May 14, 2021, Iterum issued a press release announcing its first quarter 2021 financial results (the “1Q2021 Press Release”). The 1Q2021 Press Release stated that Iterum

reported a net loss of \$98.9 million in 1Q2021 and also informed investors that the “FDA previously planned to hold an advisory committee meeting for oral sulopenem on June 2, 2021 but *this meeting was postponed to allow the FDA more time to review material provided by the Company in support of the NDA. A new date for such meeting, if required by the FDA, has not yet been confirmed.*” Despite this, the 1Q2021 Press Release also quoted Defendant Fishman as stating:

We continue to prepare for a[n FDA] advisory committee meeting and look forward to clarity from the FDA on timing. *In the meantime, the FDA continues its review of [the sulopenem NDA] and has not advised us of any change to the current PDUFA goal date of July 25, 2021. . . . With an FDA decision on oral sulopenem expected in the second half of 2021 and a strong cash position, we are preparing for a launch of oral sulopenem into the community in the fourth quarter of 2021, if approved.*

107. On the same day, Iterum filed with the SEC its quarterly report on Form 10-Q, reporting the Company’s financial results for the quarter ended March 31, 2021 (“1Q2021 10-Q”). The 1Q2021 10-Q contained substantively the same statements as the 2020 10-K, describing the data supporting the sulopenem NDA, while assuring investors that the Company had made an informed NDA submission based on prior communications with the FDA:

[I]n the uUTI trial, in the population of patients with baseline pathogens resistant to quinolones, sulopenem achieved the related primary endpoint by demonstrating superiority to ciprofloxacin, providing evidence of a treatment effect in patients with uUTI. Based on discussions with the FDA at a pre-New Drug Application, or NDA, meeting in September 2020 and previous correspondence with the FDA, we submitted an NDA for oral sulopenem for the treatment of uUTIs in patients with a quinolone non-susceptible pathogen in the fourth quarter of 2020 and the FDA accepted the application for review in January 2021.

108. The 1Q2021 10-Q also revealed that, as of March 31, 2021, Iterum had accumulated a deficit of \$385.9 million, and the Company “expect[ed] to continue to incur significant expenses for the foreseeable future as we seek regulatory approval and engage in market preparation and pre-commercialization activities.” The 1Q2021 10-Q also contained SOX certifications, signed by the Individual Defendants, which certified that “[the 1Q2021 10-Q] fully complies with the

requirements of Section 13(a) or 15(d) of the [Exchange Act]” and ***“does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]”***

109. Also on that day, Defendants held a conference call to discuss the 1Q 2021 results and made the following statements:

(a) As part of his prepared remarks, Fishman stated:

[T]he FDA review of our new drug application continues, and our interactions to date have progressed well and are typical as to where we expect to be a few months from a potential approval. . . . In closing, we believe Iterum is in a very solid position with our NDA under review and having about \$100 million of cash on the balance sheet.

(b) Regarding communications between the Company and the FDA, Fishman stated that ***“[w]e’ve been really upfront about everything that the FDA has told us.”***

110. On May 27, 2021, Iterum issued a press release updating the market on the FDA’s review of the sulopenem NDA (the “May 2021 Press Release”). The May 2021 Press Release revealed that, on May 26, 2021, Iterum participated in a “late-cycle meeting” with the FDA. The May 2021 Press Release added:

During the meeting, the FDA shared issues still under review regarding the [sulopenem NDA] and the Company responded to these issues. The FDA has determined that an Advisory Committee meeting is not currently necessary. The review of the NDA is ongoing and the Company was informed that the FDA continues to work toward the PDUFA goal date of July 25, 2021.

111. Following the May 2021 Press Release, analysts at RBC Capital Markets issued a report describing the Company’s meeting with the FDA as “[h]ealthy dialogue,” that the Company had an “open dialogue with [the] FDA,” and that the meeting was nothing more than a matter of “routine filing issues.” Specifically, the report stated:

Healthy dialogue between company and agency over path of review continues, including a recent late-cycle meeting. Per the press release and confirmed via our

discussion, the company continues to maintain an open dialogue with FDA on sharing and responding to what we interpret as routine filing issues over the course of the review.

112. Defendants' statements above in ¶¶91-111 were materially false and misleading when made. Defendants knew and/or recklessly disregarded, and failed to disclose, the following:

(a) The FDA's guidelines for a uUTI indication recommend results from two or more studies and, while a single trial, like the SURE-1 trial, can be sufficient if it is supported by data from trials in other indications, the Company's SURE-2 and SURE-3 Phase 3 studies in cUTI and intra-abdominal infections were poised to have the opposite effect since both failed to meet their primary endpoints;

(b) Iterum ran three Phase 3 studies for sulopenem across multiple indications. Two of those studies (cIAI and cUTI) missed their primary endpoint, and the third (uUTI) met only one of two co-primary endpoints. In that uUTI study, sulopenem demonstrated superiority to the quinolone antibiotic ciprofloxacin in patients with quinolone-resistant infections (62.6% vs. 36.0% overall response) but failed to meet the non-inferiority threshold in quinolone-susceptible patients (66.8% vs. 78.6% overall response), and based on interactions with the FDA during the Class Period, Defendants knew or recklessly disregarded that FDA approval of sulopenem under those circumstances was unlikely, rendering their statement about the targeted commercialization of sulopenem materially false and misleading;

(c) Since sulopenem was inferior to ciprofloxacin among quinolone-susceptible patients (66.8% vs. 78.6% clinical response), it was likely the FDA would request an additional study in quinolone-resistant uUTI with a different active comparator drug;

(d) The FDA had been resistant to approving new antibiotics in general and especially to those seeking approval outside of FDA guidelines. Iterum's sulopenem NDA fell outside FDA guidelines by seeking approval for a quinolone-resistant population based on one of

two co-primary endpoints from a single Phase 3 study, rendering it likely the Company would be required to complete an additional Phase 3 study, which would create an additional financial burden on the Company and substantially delay the Company's repeatedly stated timeline for commercialization of sulopenem;

(e) Cancellation of the FDA Advisory Committee meeting, following a late-cycle meeting with the Company, was a negative signal which substantially increased the likelihood Iterum would receive a CRL for its sulopenem NDA. Despite this, Defendants omitted disclosures of issues and concerns with the sulopenem NDA, and continued to assure investors the Company was targeting commercialization of the drug in the fourth quarter of 2021;

(f) Cancellation of the FDA Advisory Committee meeting was also a negative signal because Iterum's proposed indication for sulopenem in quinolone-resistant patients was a deviation from FDA norms, and it was unlikely with the data available that the FDA would approve sulopenem, a novel antibiotic, to treat infections that are resistant to a specific class of drugs; and

(g) Defendants' communications with the FDA, which they did not disclose to investors, indicated problems and deficiencies with the sulopenem NDA that undermined its chances for approval and threatened to not only significantly delay the Company's planned commercialization of the drug, but also to strain the Company's financial condition.

THE TRUTH UNDERLYING DEFENDANTS' FRAUD BEGINS TO EMERGE

113. In an unexpected move, on June 8, 2021, Iterum Board member Malik notified the Company of his resignation from the Board, effective immediately. Rather than replace him, Iterum chose to reduce the size of its Board.

114. Less than a month later, on July 1, 2021, the truth underlying Defendants' fraud began to emerge post-market when Iterum issued a press release announcing that the Company received a letter – which was not disclosed – from the FDA stating that, as part of the FDA's

ongoing review of the sulopenem NDA, the FDA had “identified deficiencies that preclude the continuation of the discussion of labeling and post marketing requirements/commitments at this time.” Despite receiving the letter, the Company only disclosed to investors that Iterum “intend[ed] to work with the FDA to understand the nature of the deficiencies and resolve them as quickly as possible.” Continuing, the July 1, 2021 release quoted Fishman as stating that the Company “continue[d] to believe in the potential of sulopenem,” and that the Company’s goal had shifted from approval of the sulopenem NDA to “work[ing] with the FDA to identify and resolve the issues” quickly to “continue advancing this much needed antibiotic.” Despite this development, investors were not provided any information regarding the extent of the issues, their impact on the sulopenem NDA, and whether sulopenem could still be approved by the FDA on the timeline repeatedly reiterated by Defendants throughout the Class Period.

115. On this news, Iterum’s share price fell an astounding **38%**, or \$0.87, to close at \$1.42 per share on July 2, 2021, on highly elevated trading volume. Despite this steep decline in the price of Iterum stock, Iterum stock continued to trade at artificially inflated prices because of Defendants’ uncorrected misstatements and omissions regarding the sulopenem NDA’s deficiencies.

116. Additional bad news regarding the Company’s failing sulopenem NDA shocked investors before the market opened on July 26, 2021, when Iterum issued a press release announcing that it had received a CRL regarding the sulopenem NDA from the FDA **three days earlier**, on July 23, 2021. The release described the CRL in general terms, without making it public for investors. Instead, the release stated that “[t]he CRL provided that the FDA has completed its review of the NDA and has determined that it cannot approve the NDA in its present form.” The July 26, 2021 release made clear the Company’s sulopenem NDA lacked data needed to support approval of the drug, that the Company would need to conduct an additional clinical

trial, and that the Company needed to reevaluate and determine sulopenem's optimal dosing regimen. Specifically, the press release stated:

In the CRL, the FDA acknowledged that the Phase 3 SURE-1 clinical trial demonstrated statistical significance in difference in overall response rate of oral sulopenem compared to ciprofloxacin in the ciprofloxacin-resistant population. However, *the FDA determined that additional data are necessary to support approval for the treatment of adult women with [uUTIs] caused by designated susceptible microorganisms proven or strongly suspected to be non-susceptible to a quinolone.* The FDA recommended that Iterum conduct at least one additional adequate and well-controlled clinical trial, potentially using a different comparator drug. Additionally, the FDA recommended that Iterum conduct further nonclinical investigation to determine the optimal dosing regimen, although the FDA stated that this recommendation does not raise an approvability issue. The FDA indicated its willingness to work with Iterum on the design of the clinical trial(s) to address the deficiencies noted.

117. The July 26, 2021 press release included a statement from Fishman indicating that the Company would “evaluate the points raised in the CRL for discussion with the FDA to determine an expeditious path forward.” The release added that:

Iterum intends to review the CRL with its advisors and plans to request a Type A meeting in the coming weeks. Following the Type A meeting, anticipated to be late in the third quarter, Iterum expects to provide an update on next steps as to the potential additional clinical and non-clinical work to be done prior to a resubmission of the NDA for approval of oral sulopenem.

118. On this shocking news, the price of Iterum stock plummeted, falling **44%** to close at \$0.631 per share on July 26, 2021, on unusually high trading volume.

POST-CLASS PERIOD EVENTS

119. After the Class Period ended, on November 12, 2021, the Company reported its third quarter 2021 earnings and hosted an earnings call. Discussing the sulopenem NDA, Fishman stated, in part, that Iterum had requested and recently had a “Type A” meeting with the FDA to “discuss [Iterum's CRL],” and that the FDA had informed Defendants that “the totality of [Iterum's sulopenem] NDA package was not sufficient to warrant approval for oral sulopenem at that time. . .” Fishman told investors that, “in order to have a[n NDA] package that [the FDA]

deemed potentially adequate for approval,” Iterum would need to conduct an additional Phase 3 clinical trial, assuming the Company would reach an agreement with the FDA on the design of the trial. Fishman stated the Company had requested a “Type B” meeting with the FDA so that Iterum could discuss the details of that additional Phase 3 trial, “including the protocol, endpoints and other relevant factors.” If all went well, Fishman indicated the Company would not be able to start enrolling patients in the new clinical trial until “the first half of 2022.” When asked to share information regarding the scope of the additional Phase 3 trial needed, Fishman did not provide any meaningful details, including any details regarding the deficiencies previously identified by the FDA with the sulopenem NDA.

ADDITIONAL SCIENTER ALLEGATIONS

120. The following additional facts, when considered collectively with those alleged elsewhere herein, support a strong inference that Defendants knowingly made materially false or misleading statements and/or omissions, or acted recklessly in doing so, during the Class Period.

Defendants’ Substantial Experience Supports a Strong Inference of Scienter

121. The Individual Defendants’ scienter is further demonstrated by their senior-level positions at the Company and access to material, non-public information concerning the insufficient data from the sulopenem clinical trials that was included in the sulopenem NDA, the actual results of those trials on a real-time basis, and the content of the Company’s interactions and communications with the FDA concerning the sulopenem NDA. This necessarily included the FDA’s communications with the Company during the “late-cycle meeting” between Iterum and the FDA on May 26, 2021 – approximately five months after submission of the sulopenem NDA – during which the FDA “shared issues” still under review regarding the sulopenem NDA and the Company responded to those “issues.” It also included the reasons why the FDA determined that an Advisory Committee meeting was “not currently necessary.” Likewise, it

included the content of the FDA's letter to Iterum, vaguely detailed in the Company's July 1, 2021 press release, which stated the FDA had "identified deficiencies" that "preclude[d] the continuation of the discussion of labeling and post marketing requirements/commitments at this time."

122. In fact, as referenced above, the Individual Defendants, as CEO and CFO of Iterum, each signed and submitted, as exhibits to the Forms 10-K and 10-Q filed during the Class Period, certifications under SOX certifying that the information contained therein fairly presented, in all material respects, the financial condition and operations of the Company.

123. In addition, the Individual Defendants were well-versed in matters regarding pharmaceutical company operations, including those involved in the drug approval process and interactions with the FDA. Fishman, the Company's CEO and a member of its Board, had previously been an officer with Durata, a pharmaceutical company acquired by Actavis plc, another pharmaceutical company. Fishman also previously served as an officer of GANIC Pharmaceuticals, Inc., a pharmaceutical company, and served in a variety of roles at MedPointe Healthcare, Inc., a specialty pharmaceutical company acquired by Meda AB. Fishman previously served on the boards of directors of Momenta Pharmaceuticals, Inc., a biotechnology company, from September 2016 until June 2020, and BioSpecifics Technology Corporation, a biopharmaceutical company, from April 2020 until its acquisition by Endo. Similarly, Matthews was previously the VP of Finance at Durata.

124. In addition, the Individual Defendants frequently spoke on Iterum's earnings calls regarding the status of the sulopenem NDA, Iterum's interactions with the FDA, and the Company's financial condition and outlook.

The Importance of Sulopenem and the Sulopenem NDA to the Company's Operations

125. Iterum is a clinical-stage pharmaceutical company solely focused on developing and commercializing sulopenem in the United States. At all relevant times, the Company had no other drugs in development, and Iterum incurred net losses in each year since its inception. Without successful commercialization of sulopenem, the Company would continue to incur significant financial losses and the need to potentially require additional capital to fund its operations.

126. Further, Defendants knew that, if the FDA did not approve sulopenem, Iterum faced significant additional costs, delays, and regulatory hurdles, such as additional, expensive clinical trials, which would not only worsen the Company's financial position, but potentially render the Company unable to successfully develop and commercialize sulopenem or any other product candidate.

127. For example, the Company's 2020 10-K, filed with the SEC on March 12, 2021, dedicated approximately 20 pages to describing Iterum's sulopenem program (including historical clinical trial data), the Company's sulopenem development strategy, the medical need for new drugs to combat the prevalence of bacterial resistance to antibiotics used to treat UTIs in the United States, and the market opportunity for sulopenem. Sulopenem was discussed during the Company's conference calls, SEC filings, and in market commentary and analyst reports regarding the Company. Defendants' repeated references to Iterum's development of sulopenem leading up to and during the Class Period support the inference that they had personal knowledge of issues concerning weaknesses in the clinical trial results that undermined the likelihood that the FDA would approve sulopenem, as well as the FDA's concerns with the sulopenem NDA that resulted in the CRL that Iterum disclosed to investors on July 26, 2021.

The Timing of Defendants' Statements and the Magnitude of the Fraud

128. The timing of Defendants' statements and the subsequent revelation of the fraud is also indicative of scienter. For example, Defendants' statements on November 30, 2020; January 25, 2021; March 12, 2021; May 14, 2021; and May 27, 2021 (¶¶91-111, *supra*) were made at a time when the Company was experiencing problems with the sulopenem NDA that ultimately resulted in the CRL on July 26, 2021. Defendants' communications with the FDA during this time period, which were not disclosed or adequately described to investors, stand in stark contrast to Defendants' assurances to the market that the Company was still targeting regulatory approval of sulopenem by the second half of 2021 and that Iterum was preparing to launch oral sulopenem in the fourth quarter of 2021, which would provide much-needed revenue to Iterum.

129. Specifically, on May 14, 2021, only two months before the CRL, Defendants disclosed that the FDA, which had previously planned to hold an Advisory Committee meeting for oral sulopenem on June 2, 2021, had postponed the meeting and did not set a new date for the meeting. During the Company's May 14, 2021 earnings call with investors and analysts, Fishman only disclosed that the FDA "needed more time to review the data" in Iterum's sulopenem NDA and that was why the FDA was "postponing this meeting."

130. Defendants, however, gave no indication to investors that there were problems with the sulopenem NDA and, instead, reiterated that the Company was preparing for a launch of the drug in late 2021. Indeed, during the May 14, 2021 earnings call, Fishman added that Iterum's "interactions to date" with the FDA had "progressed well" and were "typical as to where we expect to be a few months from a potential approval." Fishman added that the FDA had sent Iterum "a number of information requests" focused on "clinical and manufacturing data," but assured investors that "all of these inquiries have been addressed." Fishman added the Company was preparing for a potential launch of oral sulopenem in the fourth quarter of 2021, and highlighted

the Company's payer research and likely insurance coverage for sulopenem, indicating to investors that a lucrative launch would substantially benefit the Company. Fishman also told investors the Company would be requesting a Type B meeting with the FDA "in the next few weeks" to discuss the "potential path to regulatory approval" for sulopenem in the treatment of cUTIs. Fishman assured investors that Iterum was "in a very solid position" with the sulopenem NDA and Iterum "having about \$100 million of cash on the balance sheet."

131. But just less than two weeks later, on May 27, 2021, Defendants told investors that Iterum participated in a "late-cycle" meeting with the FDA on May 26, 2021. Defendants stated that, during the meeting, the FDA "shared issues still under review" regarding the sulopenem NDA and that the Company "responded to these issues." Defendants also disclosed that the FDA determined an Advisory Committee meeting was "not currently necessary." This meeting between the FDA and Defendants occurred exactly two months before the July 26, 2021 CRL. Thus, Defendants knew or recklessly disregarded, from their attendance at the May 26, 2021 FDA meeting, that the FDA had "issues" with the sulopenem NDA, but Defendants kept the specifics of that information hidden from investors, failed to disclose the true extent of the problems with the sulopenem NDA, and failed to correct their prior false and misleading statements which led investors to believe that sulopenem was likely to launch in late 2021.

132. Defendants were also informed via letter from the FDA, which the Company announced but did not release to the public, that the FDA had identified deficiencies with the sulopenem NDA that put a halt to discussions between the Company and the FDA regarding labeling and post marketing requirements/commitments for sulopenem. Despite prior communications with the FDA, including the "late-cycle" meeting on May 26, 2021, Defendants still failed to disclose to investors what the weaknesses were in the sulopenem NDA and whether the drug was still on track for any FDA approval.

Defendants Were Motivated to Submit the Sulopenem NDA and Maintain a Positive Market Perception of the Company

133. Defendants also were motivated to misrepresent and conceal the true likelihood of sulopenem approval to facilitate their own compensation. Specifically, in February 2020, the Company's Compensation Committee approved the grant of PSUs to Fishman (335,000 PSUs), Dunne (160,000 PSUs), and Matthews (125,000 PSUs). Notably, vesting of half of the PSUs was contingent solely on the FDA's acceptance of the sulopenem NDA, but only if that happened on or before December 31, 2021. The other half of the PSUs stood to vest on the FDA's completion of its review of the sulopenem NDA, provided that happened on or before December 31, 2021. Thus, when the FDA accepted the sulopenem NDA, which the Company announced via a press release on January 25, 2021, Fishman, Dunne, and Matthews saw 50% of their PSUs vest. Notably, Iterum stock closed at \$1.81 on January 25, 2021, more than 185% higher than its closing price of \$0.631 on July 26, 2021, after investors learned that the FDA issued a CRL in response to Iterum's sulopenem NDA.

134. Separately, while the price of Iterum stock was inflated, but before the FDA's determination on the sulopenem NDA came down, Iterum insiders, including Fishman, Dunne, and Matthews, sold significant portions of their Iterum stock holdings. On January 26, 2021, the day after Iterum announced that the FDA had accepted the sulopenem NDA for review:

(a) Fishman sold 85,445 of his shares at \$1.73 per share for total proceeds of approximately \$147,820;

(b) Matthews sold 33,868 shares at \$1.73 per share for total proceeds of approximately \$58,592; and

(c) Dunne sold 33,143 shares, also at \$1.73 per share, for total proceeds of approximately \$57,337.

135. These stock sales were unusual in both timing and amount for a few reasons. First, neither Dunne nor Fishman had ever sold any of their Iterum stock prior to January 26, 2021. Second, Matthews had only sold stock once before, on September 30, 2020. Third, the sales occurred before deficiencies in the NDA became known, allowing Iterum's insiders to recognize outsized gains compared to what they would have generated at the close of the Class Period:

	# of Shares Sold	Price/Share on 1/26/2021	Proceeds	Price/Share on 7/26/2021	Proceeds	Dollar Difference
Fishman	85,445	\$1.73	\$147,820	\$0.631	\$53,916	\$93,904
Matthews	33,868	\$1.73	\$58,592	\$0.631	\$21,371	\$37,221
Dunne	33,143	\$1.73	\$57,337	\$0.631	\$20,913	\$36,424
Total	152,456		\$263,749		\$96,200	\$167,549

136. In addition to the foregoing, Iterum required capital after consistently operating at a loss, but needed to show significant progress on the development of sulopenem and the sulopenem NDA in order to raise that capital. As alleged herein, almost immediately after announcing on January 25, 2021 that the FDA accepted the sulopenem NDA for review, Iterum then announced that it intended to conduct a series of stock offerings with gross proceeds expected to be approximately \$75 million. Defendants were motivated to misrepresent and conceal the underlying problems with the sulopenem NDA, as well as the odds of FDA approval, in order to maintain the artificial inflation in the price of Iterum stock, which would help the Company maximize the amount of capital it could raise from these offerings. Put simply, the pricing for these offerings would have been far less favorable to the Company, and attracted far less interest from investors, had the market known the truth about the sulopenem NDA and the odds of FDA rejection of the NDA.

137. These facts collectively support a strong inference that Defendants knowingly made materially false and misleading statements and omissions, or acted recklessly in doing so, during the Class Period.

LOSS CAUSATION/ECONOMIC LOSS

138. As detailed herein, Defendants' fraudulent scheme artificially inflated the price of Iterum stock by misrepresenting and concealing Iterum's business and prospects, namely problems with the sulopenem NDA and negative communications from the FDA regarding the sulopenem NDA – and by creating a false market expectation regarding the likelihood that the FDA would approve sulopenem. Later, however, as Defendants' prior misrepresentations and omissions were disclosed and became apparent to the market, the price of Iterum stock fell sharply. The failure to secure FDA approval of sulopenem negatively impacted, among other things, the Company's financial performance, including by incurring significant costs required to complete additional clinical trials, and substantially weakened Iterum's forthcoming earnings and outlook.

139. While each of Defendants' misrepresentations and omissions was independently fraudulent, they were all motivated by Defendants' desire to artificially inflate the Company's stock price and/or maintain the artificial inflation in Iterum stock and give the market the false notion that sulopenem was on track to be approved by the FDA, allowing the Company to begin commercialization of the drug in the fourth quarter of 2021, which would dramatically and positively impact the Company's financial performance and outlook. Defendants' false and misleading statements and omissions had the intended effect and caused, or were a substantial contributing cause of, Iterum stock trading at artificially inflated levels, reaching as high as \$2.73 per share during the Class Period on February 10, 2021.

140. The truth emerged through two disclosure events. First, after the market closed on July 1, 2021, the Company shocked investors by issuing a press release announcing that the FDA had identified deficiencies with the sulopenem NDA. The release stated the deficiencies were referenced in a letter from the FDA and that the deficiencies would "preclude the continuation of the discussion of labeling and post marketing requirements/commitments at this time." Notably,

the Company did not make the FDA's letter public, leaving investors unable to evaluate the nature of the deficiencies or the true extent of their impact on the viability of the sulopenem NDA or the likelihood that sulopenem could be approved by the FDA.

141. As a result of the limited information revealed to the market on July 1, 2021, the price of Iterum stock dropped approximately 38%, or \$0.87, falling from a close of \$2.29 on July 1, 2021, to a close of \$1.42 on July 2, 2021, on highly elevated trading volume of more than 82 million shares traded. The decline in price of Iterum stock was the direct result of the nature and extent of the revelations made to the market regarding the FDA letter, the deficiencies in the sulopenem NDA (which were still not described in any detail), and the news that discussions between the Company and the FDA regarding labeling and post-marketing requirements/commitments would no longer continue.

142. Additional truth reached the market on July 26, 2021, when the Company issued a press release revealing that, on July 23, 2021, Iterum received the CRL, which stated that the FDA had completed its review of the sulopenem NDA and determined that the FDA could not approve the NDA "in its present form." The Company's release revealed that "additional data are necessary" to support approval for sulopenem's treatment of adult women with uUTIs caused by designated susceptible microorganisms proven or strongly suspected to be non-susceptible to a quinolone. It also made clear that Iterum would need to conduct at least one additional adequate and well-controlled clinical trial, potentially using a different comparator drug. Additionally, the FDA recommended that Iterum conduct further nonclinical investigation to determine the optimal dosing regimen.

143. The additional news revealed on July 26, 2021 had an additional, devastating impact on Iterum's stock price. After closing at \$1.13 on July 23, 2021, Iterum stock dropped

44% to close at \$0.631 on July 26, 2021 (the next trading day), on unusually high trading volume of more than 59 million shares traded.

144. The timing and magnitude of the Iterum stock price declines on July 2 and 26, 2021, negate any inference that losses suffered by Lead Plaintiffs and other putative Class members were caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct.

145. In sum, the rapid declines in the price of Iterum stock on July 2 and 26, 2021, were the direct and foreseeable consequence of the revelation of the falsity of Defendants' Class Period misrepresentations and omissions to the market. Thus, the revelations of truth, as well as the resulting clear market reactions, support a reasonable inference that the market understood that Defendants' prior statements were misleading. In short, as the truth about Defendants' prior misrepresentations and concealments was revealed, the price of Iterum stock quickly sank, releasing artificial inflation from the stock, thereby damaging Plaintiffs and members of the Class who suffered true economic losses.

146. Accordingly, the economic losses, *i.e.*, damages, suffered by Lead Plaintiffs and Class members on July 2 and 26, 2021, were the direct and proximate result of Defendants' misrepresentations and omissions that artificially inflated the price of Iterum stock and the subsequent significant decline in the value of the stock when the truth concerning Defendants' prior misrepresentations and fraudulent conduct entered the marketplace. Notably, the price of Iterum stock has not recovered. As of January 25, 2022, the day before the filing of this Complaint, Iterum stock closed at \$0.34 per share.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE

147. At all relevant times, the market for Iterum common stock was efficient because:

(a) Iterum common stock met the requirements for listing and actively traded on the Nasdaq, a highly-efficient and automated market;

(b) According to the Company's Form 10-Q for the 3Q2021, Iterum had more than 182 million shares of common stock outstanding as of October 31, 2021, demonstrating an active and broad market for Iterum common stock;

(c) Iterum, as a regulated issuer, filed periodic public reports with the SEC;

(d) Iterum regularly communicated with public investors via established market communication mechanisms, including the regular dissemination of press releases on national circuits of major newswire services, the Internet, and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(e) Iterum was followed by numerous securities analysts employed by major brokerage firms, including RBC Capital Markets, Gabelli & Company, H.C. Wainwright & Co., LLC, and SVB Leerlink, who wrote reports that were distributed to those brokerage firms' sales forces and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

148. As a result of the foregoing, the market for Iterum common stock promptly digested current information regarding the Company from publicly-available sources and reflected such information in the price of Iterum stock. Under these circumstances, all purchasers of Iterum stock during the Class Period suffered similar injury through their purchase of Iterum stock at artificially inflated prices, and the losses they suffered when the artificial inflation was removed. Thus a presumption of reliance applies.

149. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the claims are grounded, in significant part, on Defendants' material omissions. Because

this case involves Defendants' failure to disclose material adverse information regarding facts critical to Iterum's business and operations – information that Defendants were obligated to disclose – affirmative proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of Defendants' material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

150. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false or misleading statements alleged herein. Defendants' false and misleading statements alleged herein were not forward-looking. Many of the statements alleged were not identified as "forward-looking" when made, and, to the extent any statements were forward-looking, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

151. Alternatively, to the extent that the statutory safe harbor applies to any forward-looking statements alleged, Defendants are liable for such statements because, at the time they were made, the speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Iterum who knew that the statement was false when made. Moreover, to the extent that Defendants issued any disclosures designed to warn or caution investors of certain purported risks, those disclosures were also false and misleading since they did not disclose that Defendants were actually engaging in the very actions about which they purportedly warned and/or had actual knowledge of material, adverse facts undermining such disclosures.

CLASS ACTION ALLEGATIONS

152. Lead Plaintiffs bring this case as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class consisting of all purchasers of Iterum common stock between November 30, 2020 and July 26, 2021, inclusive. Excluded from the Class are: Defendants, the current and Class Period officers and directors of the Company, the immediate family members and legal representatives, affiliates, heirs, successors-in-interest, and assigns of any such excluded person, and all entities in which any such excluded person has or had a controlling interest.

153. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Iterum common stock actively traded on the Nasdaq. According to the Company's 3Q2021 10-Q, it had more than 182 million shares of common stock outstanding as of October 31, 2021, demonstrating an active and broad market for Iterum common stock. While the exact number of putative Class members can only be determined by appropriate discovery, Lead Plaintiffs believe that Class members number at least in the hundreds, if not thousands, and that they are geographically dispersed. Record owners and other members of the Class may be identified from records maintained by Iterum or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

154. Lead Plaintiffs' claims are typical of the claims of the putative Class members because all Class members are and were similarly impacted by Defendants' wrongful conduct in violation of federal law, as alleged herein.

155. Lead Plaintiffs will fairly and adequately protect the interests of the putative Class members, and have retained counsel competent and experienced in securities class action litigation.

156. Common questions of law and fact exist as to all putative Class members and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether Defendants' publicly disseminated press releases and statements during the Class Period misrepresented and/or omitted material facts;

(c) whether Defendants failed to convey material facts or to correct material facts previously disseminated;

(d) whether Defendants participated in and pursued the fraudulent scheme or course of business complained of herein;

(e) whether Defendants acted knowingly or with severe recklessness in omitting and/or misrepresenting material facts;

(f) whether the market prices of Iterum stock during the Class Period were artificially inflated due to the material nondisclosures and/or misrepresentations complained of herein; and

(g) whether the Class members have sustained damages and, if so, what is the appropriate measure of those damages.

157. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impracticable for Class members to individually redress the wrongs done to them by Defendants. Lead Plaintiffs are not aware of any difficulty in the management of this case as a class action.

COUNT I

For Violation of §10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

158. Lead Plaintiffs repeat and re-allege the allegations in ¶¶1-157 above as if fully set forth herein. During the Class Period, Iterum and the Individual Defendants disseminated or approved the false or misleading statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

159. Iterum and the Individual Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's stock during the Class Period.

160. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and the Class members suffered damages in connection with their respective purchases of Iterum common stock during the Class Period, because, in reliance on the integrity of the market, they paid artificially inflated prices for Iterum common stock and experienced losses when the artificial inflation was released from Iterum common stock as a result of the revelations and related price declines on July 1 and 26, 2021, as detailed herein. Lead Plaintiffs and the Class would not have purchased Iterum common stock at the prices paid, or at all, if they had been aware that the market price had been artificially and falsely inflated by Defendants' false and misleading statements.

161. By virtue of the foregoing, Defendants each violated §10(b) of the Exchange Act and SEC Rule 10b-5(b) promulgated thereunder.

COUNT II

For Violation of §20(a) of the Exchange Act Against the Individual Defendants

162. Lead Plaintiffs repeat and re-allege the allegations in ¶¶1-157 above as if fully set forth herein.

163. The Individual Defendants acted as controlling persons of Iterum within the meaning of §20(a) of the Exchange Act.

164. By virtue of their high-level positions as officers and/or directors of Iterum, participation in and/or awareness of the Company's operations and/or intimate knowledge of the Company's disclosures, practices, and business operations, Defendants each had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements that Lead Plaintiffs contend are false and misleading. Defendants were provided with, or had unlimited access to copies of, the Company's public filings and other statements alleged by Lead Plaintiffs to be misleading before and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause their correction.

165. As set forth above, Iterum and the Individual Defendants violated §10(b) and Rule 10b-5 promulgated thereunder by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, and as a result of their aforementioned conduct, the Individual Defendants are liable pursuant to §20(a) of the Exchange Act for the §10(b) violations alleged herein. As a direct and proximate result of the Defendants' wrongful conduct, Lead Plaintiffs and other Class members suffered damages in connection with their purchases of Iterum stock during the Class Period, as evidenced by, among other things, the stock price declines alleged above, when the artificial inflation was released from Iterum stock.

166. By reason of such conduct, the Individual Defendants are liable pursuant to §20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs pray for relief and judgment as follows:

- A. Determining that this action is a proper class action, certifying Lead Plaintiffs as Class representatives under Rule 23 of the Federal Rules of Civil Procedure, and designating Lead Counsel as Class Counsel;
- B. Awarding compensatory damages in favor of Lead Plaintiffs and other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- C. Awarding Lead Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
- D. Awarding such further relief as the Court may deem just and proper.

JURY TRIAL DEMAND

Lead Plaintiffs hereby demand a trial by jury.

DATED: January 26, 2022

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Counsel for Lead Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that, on January 26, 2022, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses on the attached Electronic Mail Notice List, and I hereby certify that I caused the mailing of the foregoing via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

s/ Robert J. Robbins

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